UNITED STATES DISTRICT COURT
DISTRICT OF MAINE

PUTNEY, INC.,	***)***	
	)	
Plaintiff	***)***	
	)	
v.	***)***	***Docket No. 07-108-P-H***
	)	
PFIZER, INC., et al.,	***)***	
	)	
Defendants	***)***	

RECOMMENDED DECISION ON MOTIONS TO DISMISS COUNTERCLAIM AND FOR PRELIMINARY INJUNCTION

The plaintiff, Putney, Inc., moves to dismiss the counterclaims asserted by defendant Pfizer, Inc. Pfizer moves for a preliminary injunction restraining Putney from continuing to advertise, market and promote its cefpodoxime proxetil prescription medication to veterinarians and others as being approved by the Food and Drug Administration for use in animals.[1] I recommend that the court grant the motion to dismiss in part and deny the motion for a preliminary injunction.

I. Motion to Dismiss

A. Applicable Legal Standard

Putney's motion to dismiss Pfizer's counterclaims invokes Fed. R. Civ. P. 12(b)(6). Putney, Inc.'s Motion to Dismiss Pfizer's Counterclaims, etc. ("Motion to Dismiss") (Docket No.

[1] At a telephone conference held on September 18, 2007 counsel for the plaintiff and counsel for Pfizer agreed that the motion for a preliminary injunction should be decided on the papers without a testimonial hearing and that the court could decide that motion together with the motion to dismiss Pfizer's counterclaims. Report of Conference of Counsel and Order, etc. ("Report of Conference of Counsel") (Docket No. 48) at 2. Counsel for Pfizer also stated that Pfizer would not press its request for oral argument on its motion for preliminary injunction "if the court feels that such is not necessary." The parties' submissions are sufficient to present their arguments fully. The request for oral argument is denied.

26) at 5. As the Supreme Court recently has clarified:

> While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level.

Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955, 1964-65 (2007) (citations omitted).[2]

"In ruling on a motion to dismiss [under Rule 12(b)(6)], a court must accept as true all the factual allegations in the complaint and construe all reasonable inferences in favor of the plaintiffs." *Alternative Energy, Inc. v. St. Paul Fire & Marine Ins. Co.*, 267 F.3d 30, 33 (1st Cir. 2001). Ordinarily, in weighing a Rule 12(b)(6) motion, "a court may not consider any documents that are outside of the complaint, or not expressly incorporated therein, unless the motion is converted into one for summary judgment." *Id*. "There is, however, a narrow exception for documents the authenticity of which are not disputed by the parties; for official public records; for documents central to plaintiffs' claim; or for documents sufficiently referred to in the complaint." *Id*. (citation and internal quotation marks omitted).

B. Factual Background

The following relevant factual allegations are included in Pfizer's counterclaims.

Pfizer is a Delaware corporation with a principal place of business in New York City; it makes and distributes pharmaceutical products for use in humans and animals. Counterclaim ¶ 3. Putney is a Delaware corporation with a principal place of business in Portland, Maine which markets

[2] In so explaining, the Court explicitly backed away from the Rule 12(b)(6) standard articulated in *Conley v. Gibson*, 355 U.S. 41 (1957), that "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Twombly*, 127 S. Ct. at 1968 (quoting *Conley*, 355 U.S. at 45-46). The Court observed: "[A]fter puzzling the profession for 50 years, this famous observation has earned its retirement. The phrase is best forgotten as an incomplete, negative gloss on an accepted pleading standard: once a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." *Id*. at 1969.

one product, cefpodoxime proxetil, to the veterinary community. *Id*. ¶ 4. Cefpodoxime proxetil is a generic drug that has been approved by the FDA for use in humans but not for use in animals. *Id*.

Pfizer offers the prescription medication SIMPLICEF® which is used to treat canine skin infections. *Id*. ¶ 7. This drug was originally approved for use in humans under the name VANTIN®. *Id*. In 2004 SIMPLICEF® was approved by the FDA for use in the treatment of certain skin infections in dogs. *Id*. The FDA granted Pfizer exclusive rights to market SIMPLICEF® to veterinarians for use in the treatment of skin infections in dogs. *Id*. ¶ 8. The market exclusivity expires on July 22, 2009. *Id*.

In or about the first half of 2007 Putney began advertising, marketing, promoting and selling to veterinarians its only product, cefpodoxime proxetil. *Id*. ¶ 9. Putney obtains cefpodoxime proxetil from Ranbaxy Pharmaceuticals Inc. which received approval from the FDA to manufacture and market the drug for use in humans after establishing that it was the bioequivalent to VANTIN® in humans. *Id.* Putney obtains the drug from Ranbaxy at a substantially lower price than that at which it is offered to the human market. *Id*. ¶ 10. Ranbaxy packages the product with Putney's name and label and then ships it directly to Putney's distributors, who in turn sell it to veterinarians. *Id*.

Putney has been falsely communicating to veterinarians that it is authorized by the FDA to market its cefpodoxime proxetil for use in animals, that this product has been approved by the FDA as bioequivalent to Pfizer's SIMPLICEF® product in animals and thus is a generic version of SIMPLICEF®, and that the FDA has approved this product for use in animals. *Id*. ¶ 11. In fact, the FDA has not authorized Putney to market its cefpodoxime proxetil product for use in animals, has not approved the product as bioequivalent to SIMPLICEF®, has made no finding that the produce is generic SIMPLICEF® , and has not approved the product for use in animals. *Id*.

Putney is using in interstate commerce a promotional brochure to market its generic drugs, even though it has sold and is selling only one product, to veterinarians as FDA-approved for use in animals. *Id*. ¶ 12. The brochure states in capital letters at the top of the first page: "PUTNEY YOUR PARTNER FOR HIGH QUALITY FDA APPROVED GENERICS." *Id*. The brochure goes on to state: "For the first time there is a brand that stands for high quality, FDA approved drugs that are equivalent to brand name drugs at competitive prices, exclusively for veterinarians." *Id*. It also states: "We are focused on the development of high quality, true generics that are FDA approved and bioequivalent to brand drugs and important therapies where choice and competition are limited. Our goal is to launch generic versions of drugs veterinarians have requested to enable veterinarians to make prescribing decisions based on pet patient needs." *Id*. It also states that "Putney sells only FDA approved products[,]" and contains a chart that sets forth the rigorous review process administered by the FDA when reviewing a new drug application for approval. *Id*.

By repeatedly claiming that its generic drugs are FDA approved in a brochure that is covered with pictures of dogs and cats and marketed to veterinarians, Putney falsely communicates to veterinarians that it is marketing and selling a drug that is FDA-approved for use in animals, that its product has been approved by the FDA as a generic version of Pfizer's SIMPLICEF® product for animals, and that it has been authorized by the FDA to market its product for use in animals. *Id*. ¶ 13. These statements are materially false and misleading. *Id*. The Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*., and the pertinent regulation thereunder, 21 C.F.R. § 530.4, bar the advertising or promotion of extralabel uses of approved new human drugs in animals. *Id*. Putney and its distributors have been marketing, promoting and selling its drug as "generic SIMPLICEF®." *Id*. ¶ 14. In order to obtain such approval Putney would have had to file an Abbreviated New Animal Drug Application, which it has not done. *Id*. ¶ 15. Such an application would have been rejected by the FDA because it

would be unlawful for the FDA to approve such an application during Pfizer's period of market exclusivity for SIMPLICEF®. *Id*.

Putney's materially false, misleading and deceptive descriptions of fact that misrepresent the nature, characteristics and quality of its product violate section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). *Id*. ¶ 17. Putney acted willfully and with knowledge of the false and misleading nature of its marketing and advertising statements. *Id*.

Putney's conduct constitutes a knowing and willful violation of the Maine Deceptive Trade Practices Act (10 M.R.S.A. § 1211 *et seq*.) because its advertising claims create a likelihood of confusion or misunderstanding as to the sponsorship or approval of its goods and represent that its goods have characteristics and benefits that they do not have. *Id*. ¶ 21. This conduct has caused irreparable injury to Pfizer's goodwill and reputation and will continue to cause irreparable injury in the future. *Id*. ¶ 22.

By acting willfully and with knowledge of the unfair or deceptive nature of its acts and practices, Putney violated 5 M.R.S.A. § 207, causing irreparable injury to Pfizer's goodwill and reputation and will continue to cause such injury. *Id*. ¶¶ 24-26.

The conduct described above constitutes unfair competition in violation of common law. *Id.*¶ 29.

C. Discussion

1. FDA exclusivity. Putney contends that the activity on which Pfizer bases its counterclaims "falls within FDA's exclusive enforcement domain." Motion to Dismiss at 4. This is so, it asserts, because the "FDA has the final say on whether the [Federal] F[ood,] D[rug, and] C[osmetic] A[ct] ['FDCA'], the applicable provisions of the A[nimal] M[edicinal] D[rug] U[se] C[larification] A[ct of 1994] ['AMDUCA'], or FDA's implementing regulations and/or policies prohibit" the statements Putney is

alleged to have made. *Id*. at 6. It cites 21 U.S.C. § 337(a), which provides, in relevant part: "[A]ll . . . proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." No private right of action exists for a violation of the FDCA. *Ellis v. C.R. Bard, Inc.*, 311 F.3d 1272, 1284 n.10 (11th Cir. 2002); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001).

Putney asserts that the counterclaims "can be reduced to" allegations that it "is falsely communicating to veterinarians that its cefpodoxime proxetil product is FDA approved for use in animals" and that it "is purportedly marketing or promoting its cefpodoxime proxetil product for use in animals in violation of applicable federal law." Motion to Dismiss at 6 (emphasis omitted). It cites paragraphs 2, 11-13, 15-18 and 19-30 of the counterclaim. *Id*. These allegations, Putney argues, "merely turn on whether [it] is engaging in 'advertising or promotion of extralabel uses in animals of approved new animal drugs or approved human drugs' in violation of AMDUCA and applicable FDA regulations." *Id*. at 7. Because these claims "implicate and require direct application of the [FDCA], which only FDA is entitled to enforce[,]" Putney asserts, they "cannot stand." *Id*.

Pfizer responds that "federal courts have refused to dismiss Lanham Act false advertising cases that allege, as Pfizer alleges here, that the [plaintiff/counterclaim] defendant has falsely communicated that its product is FDA approved when it is not." Pfizer's Memorandum of Law in Opposition to Putney's Motion to Dismiss Pfizer's Counterclaims ("Dismissal Opposition") (Docket No. 33) at [1]. Pfizer suggests that the question common to its counterclaims is whether Putney's product has been approved for use in animals rather than whether it should be so approved, and that only the latter question requires the FDA's expertise, citing *Alpharma, Inc. v Pennfield Oil Co.*, 411 F.3d 934, 939 (8th Cir. 2005).

In fact, federal courts have not taken a uniform position on this issue. In what is perhaps the most recent discussion of the issue, the court in *Mutual Pharm. Co. v. Ivax Pharms., Inc.*, 459 F.Supp.2d 925 (C.D.Cal. 2006), pointed out that the intersection of the Lanham Act and the FDCA is an area in which the courts must "tread carefully when applying the Lanham Act to the advertising of goods . . . that are also subject to regulation by the FDCA lest it be used as a vehicle to accomplish indirectly something a party could not accomplish directly[,]" *id*. at 934.

> Thus courts have refused to allow a Lanham Act claim to proceed where, in order to determine the falsity or misleading nature of the representation at issue, the court would be required to interpret and then apply FDCA statutory or regulatory provisions. . . .
>
> On the other hand, once the FDA has taken a position on a particular matter, courts have consistently allowed the Lanham Act claim to proceed even if in determining the falsity of the alleged representation the court must make reference to the FDA action. So long as courts are not required to perform "authoritative interpretation and direct application of FDA regulations," then the simple fact that a matter touches upon an area dealt with by the FDA is not a bar to proceeding with a claim under the Lanham Act. Thus, for instance, courts have allowed Lanham Act claims to proceed when the alleged false statement was that the product has "FDA approval" because a court can test the truth of the statement without any need to interpret FDA regulations; the question will simply be whether the FDA official conferred "approval" or not.

Id. at 934-35 (citations and internal punctuation omitted). This language supports Pfizer's position, as it alleges in the counterclaim that Putney has falsely represented that its sole product has been approved by the FDA for use with animals. Counterclaim ¶¶ 11, 13, 15. However, the point has been further refined in other cases, some of which appear to favor Putney's position.

Thus, in *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130 (4th Cir. 1993), the court upheld the dismissal by the trial court of a Lanham Act claim that the defendants had falsely represented that their drugs had been properly approved by the FDA because the complaint "nowhere points to any statement or representation in the defendants' advertising which declared 'proper FDA approval[,]'"

id. at 1139. In that case, the plaintiff had contended that the act of placing a drug on the market with a packet insert often used for FDA-approved drugs implied falsely that the drug had been properly approved by the FDA. *Id*. The court held that "[s]uch a theory is, quite simply, too great a stretch under the Lanham Act." *Id.* "In order to state a proper claim for relief under § 43(a) of the Lanham Act, [the plaintiff] was required to point to *some* claim or representation that is reasonably clear from the face of the defendants' advertising or package inserts." *Id.* (emphasis in original). However, in the case at hand, Pfizer has pointed to claims and representations in the brochure that, while not explicit, are reasonably clear. The court in *Summit Tech., Inc. v. High-Line Med. Instruments Co*., 922 F. Supp. 299 (C.D.Cal. 1996) ("*Summit I*"), relied on *Mylan* in rejecting a claim that the Lanham Act was violated by a failure to disclose the allegedly illegal status of a laser system being offered for sale or that the seller would be unable to maintain the machines under FDA regulations when the FDA was in the process of investigating whether the defendants had violated its regulations by marketing the machines, *id*. at 306. Here, there is no evidence of an ongoing FDA investigation. In *Summit Tech., Inc. v. High-Line Med. Instruments Co*., 933 F. Supp. 918 (C.D.Cal. 1996) ("*Summit II*"), the same judge noted that false statements are actionable under the Lanham Act "even if their truth may be generally within the purview of the FDA[,]" *id*. at 933, but concluded again that an implied assertion that the defendants' importation of certain laser systems was legal was not actionable under the Lanham Act because the court would be required to determine whether the importation was legal, an issue that the FDA had not yet determined, *id*. at 934. I do not see anything in the challenged portions of the brochure at issue in this case that would require this court to determine an issue that either is or would be before the FDA for resolution.

Putney offers additional authority. In *Ethex Corp. v. First Horizon Pharm. Corp*., 228 F.Supp.2d 1048 (E.D. Mo. 2002), the court interpreted *Mylan* and other cases to represent a "refus[al]

to allow plaintiffs to state a claim based on implicit representations of FDA approval" and concluded, "[T]his Court thinks it inappropriate, then, to sustain a Lanham Act claim based on a representation which somehow implied FDA definitions[,]" *id*. at 1055. At first glance, this holding appears to support Putney's position; however, the court went on to say that, unlike a case in which the term at issue was clearly defined in an FDA regulation, the parties' dispute over the use of the word "generic," which is not defined in FDA regulations, meant that the court would be "forced to determine FDA policy in order to determine the truth or falsity of the 'generic' nomenclature." *Id*. I see no such need in this case. Similarly, the court in *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990), another case cited by Putney, held that it would not be appropriate for a court in a Lanham Act case "to determine preemptively how a federal administrative agency will interpret and enforce its own regulations[,]" *id*. at 231. Again, from all that appears in the record, there is in this case no question pending before the FDA that could affect the outcome of the parties' dispute, as there was in *Sandoz*. *Id*. at 230. That distinction appears to me to be critical.

Putney contends that *Alpharma* "simply does not apply here[,]" Putney, Inc.'s Reply Memorandum in Support of Its Motion to Dismiss, etc. ("Dismissal Reply") (Docket No. 45) at 2, because in that case the alleged false advertising claims were asserted after substantial regulatory proceedings before the FDA involving the claims at issue had concluded and "FDA already weighed in on the subject matter of the dispute . . . ensuring that judicial resolution of the matter would not jeopardize the consistency and uniformity of FDA regulations or otherwise impinge upon the jurisdiction of the Agency[,]" Injunction Opposition at 7 (incorporated by reference in Dismissal Reply at 2). But Putney never really describes in other than conclusory terms *how* resolution of Pfizer's counterclaims by this court will "jeopardize the consistency and uniformity of FDA regulations or otherwise impinge upon the jurisdiction of the Agency." I find persuasive and

applicable here the holding in *Alpharma*: consistency and uniformity of regulation by the FDA would not be jeopardized by judicial resolution of a case in which the issue is whether a party's drug has been approved by the FDA for a certain use, as distinct from the question whether it should be so approved. 411 F.3d at 939. There is no "should" at issue in this case in connection with the question of FDA approval. *See also Cottrell, Ltd. v. Biotrol Int'l, Inc.*, 191 F.3d 1248, 1255-56 (10th Cir. 1999) (allegation that competitor's advertising of antimicrobial pesticide falsely implied that its product had been approved or cleared by the EPA for a certain use stated a claim under Lanham Act).

The only question remaining for resolution is one raised by *Braintree Labs., Inc. v. Nephro-Tech, Inc.*, 1997 WL 94237 (D. Kan. Feb. 26, 1997), where, after reviewing the existing case law, the court said:

> It is clear that a plaintiff may not maintain a Lanham Act claim alleging only that the defendant has failed to disclose that the FDA has not approved its product. Affirmative misrepresentations, however, are generally actionable under the Lanham Act, even if the product is regulated by the FDA. Most obviously, a false statement of FDA approval is actionable. It is also clear that, because no private right of action exists under the FDCA, a plaintiff may not use the Lanham Act as an alternative vehicle by which to seek redress for an FDCA violation. Moreover, claims that require direct interpretation and application of the FDCA are not properly recognized because such matters are more appropriately addressed by the FDA, especially in light of Congress's intention to repose in that body the task of enforcing the FDCA.

Id. at *6. If the "crux" of a claim is "defendants' failure to receive FDA approval under the FDCA" the court may not consider it. *Id*. at *7. In the case at hand, I conclude that the counterclaim alleges an affirmative misrepresentation rather than merely that Putney's brochure fails to disclose that the FDA has not approved Putney's product for use in animals. The allegation of an affirmative misrepresentation means that the claim is actionable under the Lanham Act.[3]

[3] I am not persuaded by the analysis of this point in *Barr Labs., Inc. v. Quantum Pharmics, Inc.*, 1994 WL 1743983 (E.D.N.Y. Feb. 7, 1994), at *7 –*11, which seems to require an explicit assertion of FDA approval for both the drug at issue and the use of that drug at issue before a Lanham Act claim may be recognized. This approach appears to me to open a hole in the protections provided (*continued on next page*)

Putney is not entitled to dismissal of the counterclaim on this basis.

2. Pleading a Lanham Act claim. Putney next argues that Pfizer has failed to allege the elements of a Lanham Act claim in its counterclaim. Motion to Dismiss at 12-15. The applicable section of the statute provides, in relevant part:

> **(a) Civil action**
>
> **(1)** Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which —
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> * * *
>
> **(B)** in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,
>
> shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1)(B). Putney asserts that Pfizer has failed to allege an advertisement or promotion. Motion to Dismiss at 12. It contends that any inference drawn from the facts that it is a pharmaceutical company that sells drug products to veterinarians and maintains "a business brochure that describes its company[,]" to the effect that the brochure constitutes advertising or promotion as those terms are used in section 1125 is "far too attenuated and speculative to satisfy Pfizer's pleading obligations." *Id*. at 12-13. Pfizer responds that the brochure constitutes commercial advertising or promotion under First Circuit precedent. Dismissal Opposition at 10-15.

The First Circuit has held that, in order to plead a Lanham Act claim successfully under section 1125(a)(1)(B), "a plaintiff at the very least must identify some medium or means through which the defendant disseminated information to a particular class of consumers." *Podiatrist Ass'n, Inc. v. La Cruz Azul de Puerto Rico, Inc*., 332 F.3d 6, 20 (1st Cir. 2003). Pfizer's counterclaim meets this

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by the Lanham Act, at least to drug manufacturers, so large as to prevent a competitor that phrases its misleading advertising sufficiently
(*continued on next page*)

standard; it identifies the brochure, which it alleges was available on Putney's website, and which it alleges was directed at veterinarians, a particular class of consumers. It is significant in this regard that the counterclaim alleges that Putney at the relevant time had only one product on the market. The counterclaim also meets the pleading requirements for such claims set out in *Town & Country Motors, Inc. v. Bill Dodge Auto. Group, Inc.*, 115 F.Supp.2d 31, 33-34 (D. Me. 2000).[4]

Putney next contends that the Lanham Act count must fail because it fails to allege that it made the purported misrepresentations with the intent to influence potential customers. Motion to Dismiss at 13-14. "[T]he intent of influencing potential customers to purchase the speaker's goods or services" is an element of "commercial speech" under the Lanham Act, *Podiatrist Ass'n*, 332 F.3d at 19, and it is "commercial speech" that is an element of a Lanham Act claim. Read as required in connection with a motion to dismiss, Pfizer's counterclaim sufficiently alleges that the brochure constituted commercial speech. *See, e.g.*, Counterclaim ¶¶ 12-13, 17-18.

Next, Putney asserts that Pfizer's counterclaim "fall[s] well short of providing Putney with proper or sufficient notice of at least [Pfizer's] Lanham Act claims[.]" Motion to Dismiss at 14-15. It contends that the counterclaim fails to tell it "what conduct purportedly 'constitutes materially false, misleading and deceptive descriptions of fact that misrepresent the nature, characteristics and quality of [its] product[,]'" how it has acted willfully or what damage and injury Pfizer has suffered. *Id*. at 14. However, the counterclaim does in fact identify the conduct that gives rise to the Lanham Act claim and sufficiently alleges willful activity and damages. Additional information about these claims will presumably be available in discovery.

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carefully from ever being liable to the competitor it has intended to harm thereby.

[4] Contrary to Putney's brief argument, Motion to Dismiss at 13, it is not necessary that the brochure mention cefpodoxime proxetil or use the words "FDA-approved for use in animals" in order for the counterclaim to plead a cause of action under the Lanham Act. That argument would be more appropriate in the context of a motion for summary judgment.

Citing case law from three other federal district courts, Putney contends that Lanham Act claims should be subjected to a heightened pleading standard, which Pfizer's counterclaim fails to meet. *Id*. at 14-15. As Pfizer notes, Dismissal Opposition at 17, the First Circuit has held that the Supreme Court's decision in *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506 (2002), "has sounded the death knell for the imposition of a heightened pleading standard except in cases in which either a federal statute or specific Civil Rule requires that result[,]" *Educadores Puertorriqueños en Acción v. Hernández*, 367 F.3d 61, 66 (1st Cir. 2004). This court, of course, must follow the directive of the First Circuit on this point.

Putney is not entitled to dismissal of any of the counts in the counterclaim on this basis.

3. UTPA claim. Putney provides three alternative bases for dismissal of the Third Counterclaim, which asserts a claim under the Maine Unfair Trade Practices Act ("UTPA"), 5 M.R.S.A. § 207. Motion to Dismiss at 15-20. Pfizer does not respond to these arguments, and the motion to dismiss may be granted for that reason alone. *In re Compact Disc Minimum Advertised Price Antitrust Litig*., 456 F.Supp.2d 131, 152 (D. Me. 2006). Even if this were not the case, Putney's assertion that Pfizer has no right of action under the UTPA is correct. The right of action provided by the UTPA is limited to persons who purchase or lease goods, services or property primarily for a personal, family or household purpose and suffer a loss thereby as a result of the use or employment by another person of an unlawful method, act or practice. 5 M.R.S.A. § 213(1). Pfizer's counterclaim makes no attempt to allege that it falls within this group for purposes of this action, nor could it conceivably succeed in any such attempt. Putney is entitled to dismissal of the Third Counterclaim.

II. Motion for Preliminary Injunction

Having concluded that, with one exception, Pfizer's counterclaims survive Putney's motion to dismiss, I must now address Pfizer's preliminary injunction motion.

A. Applicable Legal Standard

The party moving for a preliminary injunction bears the burden of satisfying each element of a familiar four-part test: (1) it must be likely to succeed on the merits; (2) it must suffer from immediate irreparable injury without injunctive relief; (3) it must balance the equities, *i.e.* the harm to the moving party in the absence of an injunction must exceed the harm to the opposing party if the injunction is granted; and (4) the public interest must be better served by granting the injunction than by denying it. *Everett J. Prescott, Inc. v. Ross*, 383 F.Supp.2d 180, 188 (D. Me. 2005). The court must "bear constantly in mind that an '[i]njunction is an equitable remedy which should not be lightly indulged in, but used sparingly and only in a clear and plain case.'" *Saco Def. Sys. Div., Maremont Corp. v. Weinberger*, 606 F. Supp. 446, 450 (D. Me. 1985) (quoting *Plain Dealer Pub. Co. v. Cleveland Typographical Union No. 53*, 520 F.2d 1220, 1230 (6th Cir. 1975)).[5]

B. Discussion

Because I find it dispositive, I address only the second element of the applicable legal test. Pfizer seeks injunctive relief with very broad language, but the only instances of "advertis[ing], market[ing] and promot[ing] its cefpodoxime proxetil medication . . . to veterinarians and others as approved by the Food and Drug Administration . . . for use in animals," Motion of Pfizer Inc. for Preliminary Injunction, etc. ("Injunction Motion") (Docket No. 23) at 1, to which it refers specifically are a brochure, *id*. at 1-2, 5-7, and a statement on Putney's website "that it has since taken down," *id*. at 4. Pfizer alleges that the brochure "continues to be displayed on the website." *Id*. at 8. Putney

[5] Pfizer's request to strike the Supplemental Declaration of Jean Hoffman (Attachment 2 to Putney, Inc.'s Motion for Leave to File a Sur-Reply, etc. (Docket No. 40)), *see* Report of Conference of Counsel at 2, is denied. Contrary to Pfizer's assertion, Pfizer's Response to Putney's Motion to File a Sur-Reply (Docket No. 42) at 2, paragraphs 12 and 13 of the supplemental declaration do not constitute a "sudden and convenient last minute conversion [that] does not address new facts raised by Pfizer's reply." This court's Local Rule 7(c) limits a reply memorandum to "replying to new matter raised in the objection or opposing memorandum," not merely to new facts raised in a reply, and the paragraphs of the supplemental declaration at issue do respond to new matter raised by Pfizer in its reply memorandum.

responds that, if its brochure and website had provided Pfizer with a basis for relief, it has "cured" such conduct by removing the brochure and any mention of cefpodoxime from its website, discontinuing the use of the brochure and stating under oath that it will not use the brochure in the future. Putney, Inc.'s Objections to Pfizer's Motion for Preliminary Injunction (Docket No. 32) at 24. The sole function of injunctive relief, whether temporary or permanent, is to forestall future violations. *United States v. Oregon State Med. Soc'y*, 343 U.S. 326, 333 (1952). There must be "a real threat of future violation or a contemporary violation of a nature likely to continue or recur." *Id.* A "cure" or "reform" of the alleged offending conduct will suffice to demonstrate the lack of irreparable harm in connection with a request for injunctive relief, so long as the reform is total and "irrefutably demonstrated." *Pic Design Corp. v. Bearings Specialty Co.*, 436 F.2d 804, 809 (1st Cir. 1971). *See generally Hibernia Sav. Bank v. Ballarino*, 891 F.2d 370, 373 (1st Cir. 1989); *Brunswick Techs., Inc. v. Vetrotex Certainteed Corp.*, 2000 WL 761004 (D. Me. May 2, 2000), at *1.

In deciding whether an alleged wrong will be repeated, courts will consider, *inter alia*, whether the alleged past action was fraudulent, whether the defendant did not cease the allegedly wrongful activity until the institution of an investigation or the bringing of a lawsuit, the nature of the alleged past violation, whether the defendant continues to maintain that the conduct at issue was blameless, and the sincerity of the defendant's assurances that it will not repeat the alleged activity in the future. *SEC v. Manor Nursing Ctrs., Inc.*, 458 F.2d 1082, 1100-01 (2d Cir. 1972). Here, Pfizer's counterclaim does not allege fraud; Putney apparently stopped using the brochure at issue only after this action was instituted; and Putney continues to maintain that its brochure did not violate the Lanham Act, did not violate Maine's Unfair Trade Practices Act and did not constitute unfair competition under Maine common law. Answer and Counterclaims of Defendant Pfizer Inc. ("Counterclaim") (Docket No. 15) at 9-18. Pfizer contends that Putney has not "promise[d] not to repeat" its allegedly

wrongful conduct as set forth in the brochure at issue, Reply Memorandum of Law of Pfizer Inc. in Support of Its Motion for Preliminary Injunction ("Injunction Reply") (Docket No. 39) at 9. However, the statement in the affidavit of Putney's founder, president and chairman, Jean Hoffman, that "Putney does not intend to use the brochure of which Pfizer has complained again or to re-display that brochure on its web site," Supplemental Declaration of Jean Hoffman (Attachment 2 to Docket No. 40) ¶ 13, does just that. My review of Pfizer's substantive claims about the brochure leads me to the conclusion that the question whether the brochure violates any of the statutes and law cited by Pfizer is a close one; accordingly, Putney's continued protestations of blamelessness do not support a conclusion that its professions concerning its intentions with regard to the brochure are merely made in order to avoid the imposition of an injunction, with the offending conduct likely to resume.[6] For the same reason, I conclude that Putney's continued use of the allegedly offending brochure from May 29, 2007, the date of Pfizer's letter to Putney demanding that it immediately stop using the brochure, Injunction Motion at 7, to an unknown date after Putney itself brought this declaratory judgment action which was filed with this court only two weeks later (Docket No. 1), does not allow the drawing of a reasonable inference that Putney is likely to resume the use of the brochure. *See also Mutual Pharmaceutical*, 459 F.Supp.2d at 944.

Contrary to Pfizer's argument, Injunction Reply at 9, Putney need not "inform all viewers of its brochure that Putney's product is not approved for use in animals" in order to cure the wrong alleged in Pfizer's counterclaim. The brochure is no longer available to the public. Pfizer has made no attempt to demonstrate that Putney itself nonetheless continues to market its product as FDA-approved for use in animals. This is not the "clear and plain case" in which the issuance of injunctive relief before the merits of the underlying dispute are resolved can be justified.

[6] By its own account, Pfizer's exclusive right to market and promote its cefpodoxime proxetil product for use in dogs will expire on July (*continued on next page*)

III. Conclusion

For the foregoing reasons, I recommend that Putney's motion to dismiss Pfizer's counterclaim be **GRANTED** as to the count entitled Third Counterclaim and otherwise **DENIED** and that Pfizer's motion for a preliminary injunction be **DENIED**.

NOTICE

A party may file objections to those specified portions of a magistrate judge's report or proposed findings or recommended decisions entered pursuant to 28 U.S.C. § 636(b)(1)(B) for which de novo review by the district court is sought, together with a supporting memorandum and request for oral argument before the district judge, if any is sought, within ten (10) days after being served with a copy thereof. A responsive memorandum and any request for oral argument before the district judge shall be filed within ten (10) days after the filing of the objection.

Failure to file a timely objection shall constitute a waiver of the right to de novo review by the district court and to appeal the district court's order.

Dated this 17th day of October, 2007.

/s/ David M. Cohen
David M. Cohen
United States Magistrate Judge

22, 2009, Injunction Motion at 1, less than two years from now.